

present after the reaction with the analyte indicates that there was a large quantity of analyte present in the sample of material.

**[0033]** In the exemplary embodiment of the present invention, first, second, third, and fourth housing segments are disposed about a central housing segment. For clarity of description, the four housing segments are numbered in a clockwise direction. The exemplary apparatus is shown in FIG. 1. A valve is positioned to open or close off different flow paths through the central housing segment. The valve includes two positions: 1) a sample preparation position (e.g., valve 14 shown in FIG. 4A), where the valve is positioned to fluidically connect a first housing segment including a sample of material with a third housing segment, which retains “waste”, and 2) a testing position (e.g., valve 14 shown in FIG. 4B), where the valve is positioned to fluidically connect a fourth housing segment that includes a buffer solution with a second housing segment, which includes a testing device adapted to detect the analyte and provide a visual indicium of the presence or absence of the analyte.

**[0034]** Any suitable number of housing segments may be used in alternate embodiments. The number of housing segments may depend on, for example, the type of assay chemistry used. Those skilled in the art may modify the exemplary invention in order to adapt the present invention to a different type of assay.

**[0035]** FIG. 1 is a perspective view of an exemplary embodiment of apparatus 10 of the present invention, which includes frame 12, rotary valve 14 (with handle 14A), central housing segment 15 (shown in FIG. 3), first housing segment 16 (with extension tube 16A), second housing segment 18, third housing segment 20, and fourth housing segment 22. Frame 12 is a rigid material, such as cardboard, plastic, metal foil, or a combination of the same. In some embodiments, frame 12 may include a protective coating in order to help frame 12 resist fluids and to help protect frame 12 from damage due to exposure to fluids (e.g., water damage). Valve 14 is a rotary valve that includes a seal selector to selectively seal off pathways 17, 19, 21, and 23 (shown in FIG. 3) between central housing segment 15 and each of the housing segments 16, 18, 20, and 22, respectively. However, any suitable valve may be substituted for valve 14 in alternate embodiments.

**[0036]** First, second, third, and fourth housing segments 16, 18, 20, and 22, respectively, are disposed about central housing segment 15 and are in selective fluidic communication therewith. Specifically, valve 14 may be actuated in order to selectively fluidically connect two or more housing segments 15, 16, 18, 20, and 22. The capability of valve 14 to adjust flow paths through central housing segment 15 enables an operator to control when different fluids (e.g., buffers) contained within one or more housing segments 15, 16, and/or 22 are released, which may allow the operator to control when the assay is run and to control reaction times. This will be described in greater detail below.

**[0037]** In the exemplary embodiment, housing segments 15, 16, 18, 20, and 22, are formed of a single piece of a flexible film, such as a plastic film, that is attached to one side of frame 12 using any suitable method, such as a pressure sensitive adhesive. As a result of this construction, apparatus 10 has a relatively low profile (e.g., less than 2.5 centimeters thick). Preferably, the film and frame 12 are attached so as to form a leak proof assembly. Housing segments 15, 16, 18, 20, and 22 may be formed by any suitable method, including vacuum

forming a sheet of flexible film to form a plurality of blister-like housing segments and by attaching the flexible film to frame 12.

**[0038]** A general description of each housing segment will be followed by a detailed description of each housing segment and the operation of apparatus 10. Central housing segment 15 includes capture medium 24 (shown in phantom in FIG. 3), which is adapted to capture analyte from a sample of material. First housing segment 16 is configured to receive sample acquisition assembly 3, which preferably includes sample acquisition device 5 including porous medium 6, hollow shaft 7 (with first end 7A and second end 7B), and first fluid reservoir 8 in selective fluidic communication with hollow shaft 7. First fluid reservoir 8 retains first fluid 9. Second housing segment 18 includes a testing device adapted to detect presence of the analyte. Third housing segment 20 is configured to retain at least a substantial amount of a first fluid that after it is released from the first fluid reservoir. Fourth housing segment 22 includes a second fluid reservoir, which includes second fluid 25.

**[0039]** Valve 14 may be actuated between a sample preparation position and a testing position. For example, an operator may grasp handle 14A (with a tool, manually, or otherwise) to rotate valve 14. As FIG. 3 will show, without valve 14, each housing segment 15, 16, 18, 20, and 22 is fluidically connected to each other. Valve 14 is configured to selectively close off specific housing segments 16, 18, 20, and 22. Otherwise stated, depending on its rotation position relative to frame 12, valve 14 is configured to selectively close off specific pathways 17, 19, 21, and 23 between each housing segment 16, 18, 20, and 22, respectively, and central housing segment 15.

**[0040]** FIGS. 2A-2C illustrate an exemplary embodiment of valve 14 and how the seal selector feature of valve 14 opens and closes different pathways. FIG. 2A is a cross-section of an exemplary open pathway 2, which is representative of pathway 17, 19, 21, or 23. Pathway 2 is formed between frame 12 and flexible material 13, which forms each housing segment 15, 16, 18, 20, and 22. The cross-section shown in FIG. 2A is representative of a cross-section taken along line A-A in FIG. 1.

**[0041]** FIGS. 2B illustrates how rib 4 of valve 14 may be used to close pathway 2. Valve 14 may include a plurality of ribs, where each rib corresponds to a pathway 17, 19, 21, and 23. Valve 14 may be actuated to rotate rib 4 in and out of position (where in the “in position”, rib 4 is positioned within a notch 2a formed by pathway 2 in frame 12) in order to close and open pathway 2. Valve 14 is biased toward frame 12 by suitable bias means, such as a spring. Rib 4 is configured to fit within notch formed by pathway 2 as valve 14 is actuated and rib 4 passes over pathway 2. In this way, rib 4 acts as a detent for valve 14. As rib 4 fits within notch 2a, tactile and/or audible feedback is supplied to an operator that valve 14 is in a correct position. The detent also helps prevent accidental movement of valve 14, such as during shipping, storage, or during operation of apparatus 10. As seen in FIG. 3, flexible material 13 folds back on itself when rib 4 is positioned over pathway 2. It is preferred that flexible material 13 that forms each housing segment and pathway of apparatus 10 does not pinch or wrinkle as rib 4 slides into notch 2a.

**[0042]** FIG. 2C illustrates how valve 14 may be used to control a flow rate through pathway 2 by actuating rib 4 only partially over pathway 2 (shown in FIG. 2A) to form partially open pathway 102. Pathway 102 is smaller in cross-section